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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LY, CHEYNE D	
ART UNIT	PAPER NUMBER
1631	

DATE MAILED: 05/20/2003

12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/038,854	SPYTEK ET AL.	
	Examiner	Art Unit	
	Cheyne D Ly	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-41* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-4, drawn to a polypeptide, classified in class 530, subclass 350. If this Group is elected, then the below summarized sequence election is required.

II. Claims 5-13, drawn to a nucleic acid, classified in class 536, subclass 23.1. If this Group is elected, then the below summarized sequence election is required.

III. Claim 14, drawn to a cell comprising a vector, classified in class 435, subclasses 325 and 252.3. If this Group is elected, then the below summarized sequence election is required.

IV. Claims 15-17, drawn to an antibody, classified in class 530, subclass 387.1. If this Group is elected, then the below summarized sequence election is required.

V. Claim 18, drawn to a method for determining the presence or amount of a polypeptide, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

VI. Claim 19, drawn to a method for determining the presence or amount of a nucleic acid molecule, classified in class 435, subclass 6. If this Group is elected, then the below summarized sequence election is required.

VII. Claim 20, drawn to a method of identifying an agent that binds to a polypeptide, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

VIII. Claim 21, drawn to a method for identifying an agent that modulates the expression or activity of a polypeptide, classified in class 435, subclass 7.1. If this Group is elected, then the below summarized sequence election is required.

IX. Claim 22, drawn to a method of modulating an activity of a polypeptide, classified in class 514, subclass 2. If this Group is elected, then the below summarized sequence election is required.

X. Claims 23-27, drawn to a method of treating or preventing a NOVX-associated disorder, classified in class 514, subclasses 2 and 44. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized specie election is also required.

XI. Claims 28-34, drawn to a pharmaceutical composition and kit, classified in classes 514 and 435, subclasses 1 and 287.2. If this Group is elected, then the below summarized specie election is also required.

XII. Claim 35, drawn to the use of a therapeutic in the manufacture of a medicament for treating a syndrome associated with the NOVX-disorder, classified in class 514, subclasses 2 and 44. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized specie election is also required.

XIII. Claims 36 and 37, drawn to a method for screening for a modulator of activity or of latency or predisposition or a NOVX-associated disorder, classified in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is required.

XIV. Claims 38 and 39, drawn to a method for determining the presence of or predisposition to a disease with altered levels of a polypeptide, classified in class 436, subclass 64. If this Group is elected, then the below summarized sequence election is required. If this Group is elected, then the below summarized specie election is also required.

XV. Claims 40 and 41, drawn to a method of treating a pathological state in a mammal, classified in class 514, subclasses 2 and 44. If this Group is elected, then the below summarized specie election is also required. If this Group is elected, then the below summarized specie election is also required.

Sequence Election Requirement Applicable to All Groups:

2. In addition, each Group detailed above reads on patentably distinct sequences. Each sequence is patentably distinct because they are unrelated sequences, and a further restriction is applied to each Group. For an elected Group draw to amino acid/polypeptide sequence, the Applicants must further elect a single amino acid/polypeptide sequence. For an elected Group drawn to nucleotide sequences, the Applicants must elect a single nucleic sequence (See MPEP § 803.04). It is noted that the multiple of sequence submissions for examination has resulted in an undue search burden if more than one nucleic acid sequence is elected, thus making the previous waiver for up to 10 elected nucleic sequences effectively impossible to reasonably implement.

3. MPEP § 803.04 states:

4. Nucleotides sequences encoding different proteins are structurally distinct chemical compounds and are unrelated to one another. These sequences are thus deemed to normally constitute independent and distinct inventions with the meaning of 35 U.S.C. 121. Absent evidence to the contrary, each such nucleotide sequence is presumed to represent an independent and distinct invention, subject to a restriction requirement pursuant to 35 U.S.C. 121 and 37 CFR 1.141 et seq. Examination will be

restricted to only the elected sequence. It is additionally noted that this sequence election requirement is a restriction and not a specie election requirement.

SPECIE ELECTION REQUIREMENT FOR GROUP X-XII, XIV, and XV:

5. This application contains claims directed to the following patentably distinct species of the claimed invention:

Species A: Polypeptide.

Species B: Nucleic Acid.

Species C: Antibody.

6. Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 23-35 and 38-41 are generic. These species are distinct due to each having distinct critical features which are generally separately analyzed and published, and thus document the undue search burden if searched together.

7. Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

8. Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

9. Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

10. The inventions of Groups [I, V, VII, VIII, IX, X (polypeptide), XI (polypeptide), XII (polypeptide), XIII, XIV (polypeptide), XV (polypeptide)]; [II, VI, X (nucleic acid), XI (nucleic acid), XII (nucleic acid), XIV (nucleic acid), XV (nucleic acid)]; III; and [IV, X (antibody), XI (antibody), XII (antibody)] are distinct inventions because they are directed to different chemical types or methods regarding the critical limitations therein. For Groups I, V, VII, VIII, IX, X (polypeptide), XI (polypeptide), XII (polypeptide), XIII, XIV (polypeptide), and XV (polypeptide), the critical feature is a polypeptide. For Groups II, VI, X (nucleic acid), XI (nucleic acid), XII (nucleic acid), XIV (nucleic acid), XV (nucleic acid), the critical feature is a nucleic acid. For Group III, the critical feature is a cell. For Group III, the critical feature is a cell. For Groups IV, X (antibody), XI (antibody), and XII (antibody), the critical feature is an antibody. Further, it is acknowledged that various processing steps may cause a polypeptide of the claims in Group I and an antibody of the claims of Group IV to be directed as to its synthesis by the nucleic acid set forth in Group II, however, the completely distinct critical features of each Group of inventions support the undue search burden if they were examined together. Additionally, polypeptide, nucleic acids, antibodies, and their methods of use have been most commonly, albeit not always, separately characterized and published in the Biochemical

literature, thus significantly adding to the search burden if examined together as compared to being search separately.

11. Inventions in Groups I, V, VII, VIII, IX, X (polypeptide), XI (polypeptide), XII (polypeptide), XIII, XIV (polypeptide), and XV (polypeptide) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the amino acid of Group I may be utilized in the distinct usages as needed in Group V, a method for determining the presence or amount of a polypeptide. As needed in Group VII, which is a method of identifying an agent that binds to a polypeptide. As needed in Group VIII, which is a method for identifying an agent that modulates the expression or activity of a polypeptide. As needed in Group IX, which is a method of modulating an activity of a polypeptide. As needed in Group X (polypeptide), which is a method of treating or preventing a NOVX-associated disorder. As in Group XI (polypeptide), which is a pharmaceutical composition and kit. As needed in XII (polypeptide), which is the use of a therapeutic in the manufacture of a medicament for treating a syndrome associated with the NOVX-associated the NOVX-disorder. As needed in Group XIII, which is a method for screening for a modulator. As needed in Group XIV (polypeptide), which is a method for determining the presence of or predisposition to a disease with altered levels of a polypeptide. As needed in Group V (polypeptide), which is a method for treating a pathological state in a mammal, or alternatively, a polypeptide may be used in a method for determining the degree of affinity between a ligand and its respective receptor in competitive binding assays, for

example. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

12. Inventions in Groups II, VI, X (nucleic acid), XI (nucleic acid), XII (nucleic acid), XIV (nucleic acid), and XV (nucleic acid) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the nucleic acid molecule of Group II may be utilized in the distinct usages as needed in Group VI, which is method for determining the presence or amount of a nucleic acid molecule. As needed in Group X (nucleic acid), which is a method of treating or preventing a NOVX-associated disorder. As in Group XI (nucleic acid), which is a pharmaceutical composition and kit. As needed in XII (nucleic acid), which is the use of a therapeutic in the manufacture of a medicament for treating a syndrome associated with the NOVX-associated the NOVX-disorder. As needed in Group XIV (nucleic acid), which is a method for determining the presence of or predisposition to a disease with altered levels of a polypeptide. As needed in Group V (nucleic acid), which is a method for treating a pathological state in a mammal, or alternatively, as an antisense therapy. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

13. Inventions in Groups are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant application, the antibody of Group IV may be utilized in the distinct usages as needed in Group X (antibody), which is a method of treating or preventing a NOVX-associated disorder. As in Group XI (antibody), which is a pharmaceutical composition and kit. As needed in XII (antibody), which is the use of a therapeutic in the manufacture of a medicament for treating a syndrome associated with the NOVX-associated the NOVX-disorder, or alternatively, as a tool for antigen localization studies. All of these usages are distinct as requiring distinct and different functions and results thereof without overlapping search due to different subject matter. This lack of overlapping searches documents the undue search burden if they were search together.

14. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

15. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

16. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the

application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

17. Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 193), and 1157 OG 94 (December 28, 1993) (see 37 CFR § 1.6(d)). The CM1 Fax Center number is either (703) 308-4242 or (703) 305-3014.

18. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (703) 308-3880. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

19. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward, Ph.D., can be reached on (703) 308-4028.

20. Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner, Tina Plunkett, whose telephone number is (703) 305-3524 or to the Technical Center receptionist whose telephone number is (703) 308-0196.

C. Dune Ly
5/15/03